DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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SOLICITOR

NOV 01 1988

U.S. PATENT & TRADEMARK OFFICE

OCT 27 1988

Re: Novantrone
Docket No. 88E-0132
U.S. Pat. No. 4,197,249

Charles E. Van Horn, Esq.
Deputy Solicitor
Solicitor's Office
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the patent term extension application for U.S. Patent No. 4,197,249 filed by American Cyanamid Company under 35 U.S.C. 156. The patent claims the human drug product named Novantrone (mitoxantrone hydrochloride), New Drug Application number 19-297.

In the April 22, 1988 issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). The notice provided that on or before October 19, 1988, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to the notice regarding Novantrone has expired, and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Alphone R. Noe, Manager
Patent Law Department
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